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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,373	12/03/2003	Jeffrey Schlom	38163-0197	5890

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OFFICE OF TECHNOLOGY TRANSFER  
NATIONAL INSTITUTES OF HEALTH  
C/O HELLER EHRMAN WHITE & MCAULIFFE LLP  
1717 RHODE ISLAND AVENUE, NW  
WASHINGTON, DC 20036-3001

EXAMINER
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DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
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1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/725,373

Applicant(s)

SCHLOM ET AL.

Examiner

DiBrino Marianne

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 47-50, 52-54, 56, 58 and 59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-50, 52-54, 56, 58 and 59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                 |                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                            | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/8/07</u> . | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

1. Applicant's amendment filed 2/8/07 is acknowledged and has been entered.
2. Claims 47-50, 52-54, 56, 58 and 59 read on the elected species SEQ ID NO: 2, and are presently being examined.
3. Applicant is reminded that incorporation of *essential* material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The attempt to incorporate subject matter into the instant application by reference to foreign patents and non-published foreign patent applications on page 45 is improper because an application as filed must be complete in itself in order to comply with 35 USC 112. An application for a patent when filed may incorporate "essential material" by reference to (1) a US patent or (2) a US patent application publication, which patent or patent publication does not itself incorporate such essential material by reference. "Essential material" is defined as that which is necessary to (1) provide a written description of the claimed invention, and the manner and process of making and using it, in such full, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention, (2) describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 USC 112, or (3) describe the structure, material or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 USC 112. In any application which is to issue as a US patent, essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non-patent publications, (3) a US patent or application which itself incorporates "essential material" by reference, or (4) a foreign application. See *In re Fouché*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971).

*Nonessential subject matter may be incorporated by reference to (1) patents or applications published by the US or foreign countries or regional patent offices, (2) prior and concurrently filed, commonly owned US applications, or (3) non-patent publications.* Nonessential subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art.

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Applicant is invited to determine whether material incorporated by reference is essential or non-essential and amend the specification accordingly. (See MPEP 608.01(p)).

The following are new grounds of rejection necessitated by Applicant's amendment filed 2/8/07.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 52, 58 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendatory material that is not supported by the specification and claims as originally filed is as follows:

- A kit comprising the vector of claim 48, *i.e.*, comprising a vector comprising a nucleic acid molecule encoding an amino acid sequence consisting of a sequence selected from the group consisting of SEQ ID NO: 2, 3, 4 and 5.
- A composition comprising the nucleic acid molecule of claim 47, *i.e.*, comprising a nucleic acid molecule encoding an amino acid sequence consisting of a sequence selected from the group consisting of SEQ ID NO: 2, 3, 4 and 5.

Applicant points to support (on page 5 of Applicant's amendment filed 2/8/07) for the claim amendments in the specification at page 6, lines 22-31 and page 7, line 30 - 32 and at page 19, line 18 to page 20, line 16.

It is the Examiner's position that the cited disclosure does not provide support for a kit comprising a vector comprising a nucleic acid molecule encoding the claimed CEA agonist peptide, nor for a composition comprising a nucleic acid molecule encoding the claimed CEA agonist peptide.

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6. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the Applicant had possession at the time of invention of the claimed kit comprising an agonist peptide and a vector comprising a gene encoding CEA or a recombinantly produced CEA protein recited in instant claim 53.

The instant claims encompass a kit comprising any CEA agonist peptide and a vector comprising a gene encoding CEA *or a recombinantly produced CEA protein* and any immunostimulatory molecule. There is insufficient disclosure in the specification on such an invention.

The specification does not disclose the definition of "a CEA protein." The specification discloses that the human CEA is a 180 kD glycoprotein expressed on the majority of colon, rectal, stomach and pancreatic tumors, some breast carcinomas, and a majority of lung carcinomas, in fetal gut tissue and to a lesser extent on normal colon epithelium.

The specification discloses that gene for the human CEA protein has been cloned, and references a non-patent literature reference and a foreign application (especially page 2 at lines 4-22). The disclosed use for the nucleic acid molecules is in cancer immunotherapy, by inducing a CTL immune response to CEA to the nucleic acid encoded agonist peptides SEQ ID NO: 2-5 (of parental peptide CAP-1 altered at non-MHC anchor residues) that will bind to HLA-A2 and elicit an immune response equal to or superior to the parental peptide (especially pages 6-8 at summary of the invention).

Evidentiary reference Anderton (Immunology 2001, 104: 367-376) teaches that *in vivo* use of altered peptide ligands is unpredictable and dangerous in outbred human populations (especially paragraph spanning columns 1 and 2 on page 370). Anderton further teaches that often T cells are produced *in vitro* and are dominant *in vitro* because they are robust enough to withstand the selective pressures of cloning, but they are not representative of the entire *in vivo* repertoire.

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The instant disclosure does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera, including a kit comprising *any* agonist peptide and a vector comprising a gene encoding CEA *or a recombinantly produced CEA protein* and *any* immunostimulatory molecule. Since the disclosure fails to provide sufficient relevant identifying characteristics, and because the genus is highly variant, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus as broadly claimed.

7. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification has not enabled the breadth of the claimed invention because the claims encompass kit comprising *any* CEA agonist peptide and a vector comprising a gene encoding CEA *or a recombinantly produced CEA protein* and *any* immunostimulatory molecule. The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed kit can be made and/or used.

The specification does not disclose the definition of a CEA protein. The specification discloses human CEA is a 180 kD glycoprotein expressed on the majority of colon, rectal, stomach and pancreatic tumors, some breast carcinomas, and a majority of lung carcinomas, in fetal gut tissue and to a lesser extent on normal colon epithelium.

The specification discloses that gene for the human CEA protein has been cloned and references a non-patent literature reference and a foreign application (especially page 2 at lines 4-22). The disclosed use for the nucleic acid molecules is in cancer immunotherapy, by inducing a CTL immune response to CEA to the nucleic acid encoded agonist peptides SEQ ID NO: 2-5 (of parental peptide CAP-1 altered at non-MHC anchor residues) that will bind to HLA-A2 and elicit an immune response equal to or superior to the parental peptide (especially pages 6-8 at summary of the invention):

Evidentiary reference Anderton (Immunology 2001, 104: 367-376) teaches that *in vivo* use of altered peptide ligands is unpredictable and dangerous in outbred human populations (especially paragraph spanning columns 1 and 2 on page 370). Anderton further teaches that often T cells are produced *in vitro* and are dominant *in vitro* because they are robust enough to withstand the selective pressures of cloning, but they are not representative of the entire *in vivo* repertoire.

It is unpredictable which altered peptide ligands from human CEA or other CEA protein would correlate with agonist activity, or which protein sequences other than the human CEA disclosed in the instant specification are "CEA protein," and which structures are immunostimulatory molecules.

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There is insufficient guidance in the specification as to how to make and/or use instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

8. For the purpose of prior art rejections, the filing date of the instant claims 52, 58 and 59 is deemed to be the filing date of the instant application, *i.e.* 12/3/03, as the parent applications do not support the claimed limitations of the instant application as enunciated at item #5 of this Office Action *supra*. For the purpose of prior art rejections, the filing date of the instant claims 47-50, 53, 54 and 56 is deemed to be the filing date of the 60/061,589 parent application, *i.e.*, 10/10/97:

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 52, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/34494.

WO 00/34494 A1 teaches a vector comprising a nucleic acid sequence that encodes the amino acid sequence of a target antigenic peptide such as the CAP1-6D peptide YLSGADLNL which is SEQ ID NO: 2 of the instant claims, or said nucleic acid sequence and vector further comprises a polypeptide comprising the amino acid sequence of at least three costimulatory molecules. WO 00/34494 A1 teaches kits containing recombinant vectors comprising the said nucleic acid molecules, host cell comprising the said nucleic acid molecules and vectors comprising the said nucleic acid molecules, for example avipox, suipox, capripox, vaccinia. WO 00/34494 A1 teaches a kit for use in making a recombinant poxvirus comprising a bacterial plasmid vector that comprises the said nucleic acid sequence. WO 00/34494 A1 teaches compositions comprising more than one nucleic acid sequence encoding target antigens such as CEA or CAP1-6D. WO 00/34494 A1 teaches that the viral vectors comprising a tumor associated antigenic peptide may be used to stimulate an immune response *ex vivo* in autologous CD8<sup>+</sup> lymphocytes before being adoptively transferred back into the cancer patient. WO 00/34494 A1 teaches that a target antigen or epitope peptide may be provided endogenously via the vector for tumors in which the antigen is expressed at low levels or absent, the providing being either *in vivo* or *ex vivo*. WO 00/34494 A1

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teaches that after immunization, the efficacy of the vaccine containing the vector encoding the tumor associated antigenic peptide may be assessed by the production of immune cells that recognize the antigen as assessed by cytolytic activity or cytokine production (especially abstract, page 2 at lines 17-20, Summary of the Invention on pages 4-10, page 11 at lines 1-7, page 21 at lines 18-30, page 22, page 23 at lines 1-3, page 25 at lines 18-32, page 26, page 27, page 28 at lines 1-5, pages 45-35, pages 36 at lines 20-32, page 37 at lines 1-4 and 17-20, page 39 at lines 16-32, page 40 at lines 16-32, page 41, paragraph spanning pages 42-43, and claims.)

Applicant's arguments are of record in Applicant's amendment filed 2/8/07 on page 8.

Applicant's arguments have been fully considered, but are not persuasive.

It is the Examiner's position that the instant claims do not have the priority date of the 60/061,589 parent provisional application as enunciated at item #5 of this Office Action.

11. Claims 52, 58 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0019195 A1.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US 2004/0019195 A1 discloses a vector comprising a nucleic acid sequence that encodes the amino acid sequence of a target antigenic peptide such as the CAP1-6D peptide YLSGADLNL which is SEQ ID NO: 24 of US 2004/0019195 A1 and SEQ ID NO: 2 of the instant claims, or said nucleic acid sequence and vector further comprises a polypeptide comprising the amino acid sequence of at least three costimulatory molecules. US 2004/0019195 A1 discloses kits containing recombinant vectors comprising the said nucleic acid molecules, host cell comprising the said nucleic acid molecules and vectors comprising the said nucleic acid molecules, for example avipox, suipox, capripox, vaccinia. US 2004/0019195 A1 discloses a kit for use in making a recombinant poxvirus comprising a bacterial plasmid vector that comprises the said nucleic acid sequence. US 2004/0019195 A1 discloses compositions comprising more than one nucleic acid sequence for target antigens such as CEA and CAP1-6D (see entire document especially abstract, [0001], [[0021]-[0025], [0029], [0037], [0046], [0018], [0011], [0120]-[0121], [0123], [0125], [0138], [0141], [0146], Table 1, [0157], [0166], [0172], [0176]-[0180], and claims 18, 19, 26, 27, 35, 36 and 68-73).

Applicant's arguments are of record in Applicant's amendment filed 2/8/07 on page 9.



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Applicant's arguments have been fully considered, but are not persuasive.

It is the Examiner's position that the instant claims do not have the priority date of the 60/061,589 parent provisional application as enunciated at item #5 of this Office Action.

12. Claims 52, 58 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,969,609 B1.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

U.S. Patent No. 6,969,609 B1 discloses a vector comprising a nucleic acid sequence that encodes the amino acid sequence of a target antigenic peptide such as the CAP1-6D peptide YLSGADLNL which is SEQ ID NO: 24 of U.S. Patent No. 6,969,609 B1 and SEQ ID NO: 2 of the instant claims, or said nucleic acid sequence and vector further comprises a polypeptide comprising the amino acid sequence of at least three costimulatory molecules. U.S. Patent No. 6,969,609 B1 discloses kits containing recombinant vectors comprising the said nucleic acid molecules, host cell comprising the said nucleic acid molecules and vectors comprising the said nucleic acid molecules, for example avipox, suipox, capripox, vaccinia. U.S. Patent No. 6,969,609 B1 discloses a kit for use in making a recombinant poxvirus comprising a bacterial plasmid vector that comprises the said nucleic acid sequence. U.S. Patent No. 6,969,609 B1 discloses compositions comprising more than one nucleic acid sequence encoding target antigens such as CEA or CAP1-6D. U.S. Patent No. 6,969,609 B1 discloses that the viral vectors comprising a tumor associated antigenic peptide may be used to stimulate an immune response *ex vivo* in autologous CD8<sup>+</sup> lymphocytes before being adoptively transferred back into the cancer patient. U.S. Patent No. 6,969,609 B1 discloses that a target antigen or epitope peptide may be provided endogenously via the vector for tumors in which the antigen is expressed at low levels or absent, the providing being either *in vivo* or *ex vivo*. U.S. Patent No. 6,969,609 B1 discloses that after immunization, the efficacy of the vaccine containing the vector encoding the tumor associated antigenic peptide may be assessed by the production of immune cells that recognize the antigen as assessed by cytolytic activity or cytokine production (especially entire document especially abstract, column 1 at lines 52-67, column 2 at lines 1-67, column 5 at lines 35-42, column 6 at lines 7-67, column 7 at lines 1-62, column 17 at lines 27-67, column 8 at lines 1-44, column 22 at lines 32-50, column 23 at lines 5-67, column 24, column 25 at lines 1-59, paragraph spanning columns 26-27, column 27 at lines 10-67, column 28 at lines 1-44 and 55-65, claim 16).

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Applicant's arguments are of record in Applicant's amendment filed 2/8/07 on page 9.

Applicant's arguments have been fully considered, but are not persuasive.

It is the Examiner's position that the instant claims do not have the priority date of the 60/061,589 parent provisional application as enunciated at item #5 of this Office Action.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 47-49, 58 and 59 are provisionally rejected under the judicially created doctrine of double patenting over claims 18, 19, 26, 27 and 35 of copending Application No. 10/406,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because the vector of instant claims 48 and 49 are nucleic acids that comprise the nucleic acid of instant claim 47, and the vector of '317 is also a nucleic acid that comprises a nucleic acid that comprises a nucleic acid sequence encoding SEQ ID NO: 2 of the instant claims (SEQ ID NO: 24 of '317). Also, although the vector of the '317 claims 18, 19, 26 and 27 also comprise additional coding sequences, the said vector comprises a nucleic acid molecule that encodes SEQ ID NO: 2. Instant claim 49 is included in this rejection because the poxviruses orthopox, avipox, capripox and suipox are obvious variants of vector as evidenced by claims 11 and 14 of '317. Instant claims 58 and 59 are included in this rejection because they are encompassed by the composition recited in claim 35 of '317, and the composition comprising the vector comprises the nucleic acid molecule encoding a tumor antigen of the claim 35 of '317.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

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Applicant's arguments are of record in Applicant's amendment filed 2/8/07 on pages 9-10.

Applicant's arguments have been fully considered, but are not persuasive.

It is the Examiner's position that the instant rejection may not be held in abeyance.

15. Claims 50, 52, 54 and 56 are provisionally rejected under the judicially created doctrine of double patenting over claims 18, 19, 26, 27 and 35 of copending Application No. 10/406,317 as applied to claims 47-49 and 57-59 above, and further in view of US 6,319,496 B1 and WO 91/02805 A2.

The claims 18, 19, 26, 27 and 35 of copending Application No. 10/406,317 do not recite wherein the vector further comprises a nucleotide sequence encoding HLA-A2 and is comprised in a kit.

US 6,319,496 B1 discloses making suipox, avipox, capripox or orthpox viral vectors comprising a nucleic acid sequence encoding CEA or one of the CAP-1-CAP10 peptides and a host cell comprising said vector, and that HLA-A2 is the restriction element for the CAP1-CAP-10 peptides, and that tumor cells that express HLA-A2 were capable of presenting the peptides (especially column 3 at lines 1-13, column 4 at lines 45-65, abstract).

WO 91/02805 A2 teaches transfecting tumor cells with a recombinant viral vector construct that directs expression of both a tumor antigen or portion thereof and an MHC protein such as an MHC class I protein that is capable of presenting the tumor antigen or portion thereof in order to stimulate CTL in a subject animal. WO 91/02805 A2 teaches that this is advantageous in augmenting antigen presentation in tumor cells that have reduced levels of MHC proteins and a reduced ability to stimulate an immune response (especially Summary of the Invention on pages 5-7 (through line 29)).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have constructed the viral vector of claims 18, 19, 26, 27 and 35 of '317 to further comprise nucleic acid sequence encoding HLA-A2 as per the teaching of WO 91/02805 A2 of making a recombinant viral vector that directs expression of both a tumor antigen or peptide thereof and the MHC class I protein that presents it, and to have placed the said vector into a kit.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because '317 teaches a vector comprising nucleic acid encoding the CAP1-6D peptide analog, and US 6,319,496 B1 discloses transfecting host cells with vectors encoding CAP antigenic peptide(s), and making compositions comprising the nucleic acid molecules. One of ordinary skill in the art at the time the invention was made would have been motivated to put the resulting vector in a kit for ease of use in

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transforming host cells such as per the disclosure of US 6,319,496 B1 of using a vector encoding the antigenic peptide to transfect a host cell. In addition, one of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to transfect tumor cells that had down-regulated their HLA-A2 molecules to evade detection because WO 91/02805 A2 teaches making a recombinant viral vector that directs expression of both a tumor antigen or peptide thereof and the MHC class I protein that presents it in order to augment antigen presentation in tumor cells.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Applicant's arguments are of record in Applicant's amendment filed 2/8/07 on pages 10-11.

Applicant's arguments have been fully considered, but are not persuasive.

It is the Examiner's position that the instant rejection may not be held in abeyance.

16. Claims 47-50, 52, 54, 56, 58 and 59 are directed to an invention not patentably distinct from claims 18, 19, 26, 27 and 35 of commonly assigned application serial no. 10/406,317, as enunciated at items # 12 and #13 supra.

Applicant's arguments are of record in Applicant's amendment filed 2/8/07 on page 11.

Applicant's arguments have been fully considered, but are not persuasive.

It is the Examiner's position that the instant rejection may not be held in abeyance.

17. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 10/406,317, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

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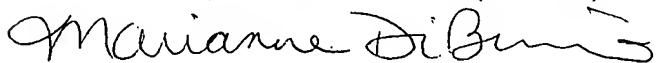
18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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April 9, 2007



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